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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,723	12/17/2001	Kenya Shitara	249-243	6052

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,723

Applicant(s)

SHITARA ET AL.

Examiner

James L. Grun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004 and 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 13-20 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 13-20 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12132004</u> . | 6) <input type="checkbox"/> Other: _____ |

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 21 March 2005 is acknowledged and has been entered. Claim 66 is newly added. Claims 1-10, 12, and 21-65 have been cancelled. Claims 11, 13-20, and 66 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The information disclosure statement (IDS) filed 13 December 2004 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered. However, the EP document and the first three non-patent literature references listed in the IDS filed 13 December 2004 are already of record in the case and have been fully considered previously (see initialed copy of IDS filed 29 March 2002 mailed 21 September 2004).

As requested, a response to applicant's supplemental submission filed 20 October 2004 has been fully provided in the Interview Summary mailed 25 October 2004. Further, the lined-through non-patent document on the copy of the IDS filed 17 December 2001 mailed 21 September 2004 is duplicative of the document listed on the initialed copy of the IDS filed 29 March 2002 mailed 21 September 2004 and has been fully considered to the extent of the information (title, etc.) contained in the provided document. Moreover, in the absence of a copy of the relevant foreign patent publication (on which the instant inventors were co-inventors), and

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in the interest of providing a complete listing of the relevant documents, see the prior art of interest listed below and on the attached form PTO-892.

The disclosure is objected to because of the following informalities: the specification is replete with grammatical, idiomatic, and spelling errors and should be carefully revised. Appropriate correction is required.

Applicant's arguments filed 21 March 2005 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's argument to the contrary, the objection to the disclosure was not non-specific. The examiner, as requested by applicant, cannot specifically list all the errors because the specification is lengthy (160 pages) and the errors are too numerous (see, **for example**: the sentence bridging pages 3-4; first full paragraph page 4; page 4, lines 23-26; etc.).

Claims 15-18 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record set forth in the prior rejection of these claims wherein a deposit requirement was made and applicants were deemed not to be in compliance with the Deposit rules. The copy of the receipt form sent by the International Depositary Authority is sufficient to show that viable cell lines were deposited under the terms of the Budapest Treaty. However, applicants have not provided the proper assurances that the cell lines will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and that the cell lines will be replaced should they ever become non-viable. The copy of the form sent by the International

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Depository Authority is not sufficient for the above assurances which must come from applicant, the attorney of record, or assignee.

Applicant's arguments filed 21 March 2005 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's argument to the contrary, the deposits are not fully in compliance for the reasons set forth above, and complete deposit information has not been provided for some of the cell lines, in particular those disclosed on pages 40-41.

The specification is objected to and claims 17 and 18 are rejected under 35 U.S.C. § 112, first paragraph, because the instant claims contain subject matter which was not described in the specification, as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention as is now claimed.

With regard to these claims, the specification, as originally filed, does not provide support for chimeric or CDR-grafted antibodies comprising DNA as is now claimed. Although one of skill in the art might realize from reading the disclosure that human and chimeric antibodies encoded by DNA from functional hybridomas are useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that antibodies comprising DNA were originally contemplated as part of applicant's invention and such does not satisfy the written description requirements of 35 U.S.C. ' 112, first paragraph. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

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Claims 11, 13-20, and 66 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 13-20 and 66 are method claims and, as such, they should clearly set forth the various method steps in a positive, sequential manner using active tense verbs, such as mixing, reacting, and detecting, delimiting how the method is actually practiced. A method claim should also clearly state each component used in the method and the relationship of the various components. In the instant claims it is not clear how one detects monocytes or macrophages or their differentiation with a single contacting step. Essential steps, such as active detecting steps for monocytes or macrophages and their differentiation, appear lacking in the instant claims. A method claim should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim. These claims are confusing because the relationship of detecting monocytes or macrophages to detecting differentiation is not clear.

Applicant's arguments filed 21 March 2005 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's argument to the contrary, all rejections under this statute have not been obviated by applicant's amendments for the reasons set forth above.

Claims 11, 13-20 and 66 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Shitara et al. (EP 0,882,799) for reasons of record in the prior rejection of the similar subject matter of claims 1-31.

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Claims 11, 13-20 and 66 are rejected under 35 U.S.C. § 102(e)(2) as being clearly anticipated by Shitara et al. (U.S. Pat. No. 6,617,160) for reasons of record in the prior rejection of the similar subject matter of claims 1-31.

Claims 11, 13-20 and 66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Shitara et al. (EP '799) or Shitara et al. (US '160) in view of Kendall et al. (U.S. Pat No. 5,861,484), and either of Clauss et al. or Barleon et al. for reasons of record in the prior rejection of the similar subject matter of claims 1-31.

Claims 11, 13-20 and 66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Shitara et al. (EP '799) or Shitara et al. (US '160) in view of Kendall et al. (U.S. Pat No. 5,861,484), either of Clauss et al. or Barleon et al., and further in view of Rockwell et al. (U.S. Pat. No. 5,840,301) for reasons of record in the prior rejection of the similar subject matter of claims 1-31.

Applicant's arguments filed 21 March 2005 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's argument to the contrary, the references performed all the method steps as positively recited in the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., detecting differentiation of hematopoietic cells into macrophages/monocytes) are not recited in the rejected claim(s) other than in the preamble. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and

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where, as herein, the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Shitara et al. (WO 98/22616) is the Japanese language parent application of U.S. C-I-P application Serial No. 09/119,014 that issued to Shitara et al. as U.S. Pat. No. 6,617,160 B1.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.

June 8, 2005



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06/10/05